K080307

510(k) Summary of Safety and Effectiveness

MAY - 1 2008

510(k) Notification
ProChem Indicator Tape – Process Indicator

Submitted by:	Raven Biological Laboratories 8607 Park Drive Omaha, NE 68127
Contact:	Wendy Royalty-Hann Quality Assurance/Regulatory Affairs Manager Or Robert V. Dwyer, Jr. President Phone: (402) 593-0781 Fax: (402) 593-0921
Prepared on:	
Device:	Trade name: ProChem Indicator Tape, Models CI-STP, CI-STP-EA, CI-STP 12, CI-STP-12EA, CI-STP-24, CI-STP-24EA Common name: Physical/chemical sterilization process indicator
Classification:	Class II
Predicate Device:	Steritec Sterilization Process Indicator Tapes Models CI 122 and CI 123, 510(k) #K003002

DEVICE DESCRIPTION

ProChem Indicator Tape is a saturated crepe paper printed with white indicator lines that turn to dark brown/black upon exposure to saturated steam or Chemiclave® chemical vapor sterilization. It is coated on the back with a dry natural rubber based adhesive for adherence to packs/packages.

INTENDED USE

ProChem Indicator Tape is process chemical indicator tape designed to hold packages together and distinguish processed packages/trays from unprocessed packages/trays.

TECHNOLOGICAL CHARACTERISTICS

The ProChem Indicator Tape consists of a saturated crepe paper printed with white indicator lines that turn to dark brown/black once an autoclave process or Chemiclave® chemical vapor process is completed. The tape is coated on the back with a dry natural rubber based adhesive.

PERFORMANCE TESTING AND SUBSTANTIAL EQUIVALENCE

Performance testing was conducted in accordance with ANSI/AAMI/ISO 11140-1:2005 in an AAMI compliant steam resistometer using 3 separate production lots of chemical indicator tapes. The performance of the ProChem Indicator Tape was equivalent to that of the predicate device and meets the requirements of Class 1 indicators as defined in ANSI/AAMI/ISO 11140-1:2005.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 1 2008

Ms. Wendy Royalty-Hann
Quality Assurance/ Regulatory Affairs Manager
Raven Laboratories, Incorporated
8607 Park Drive
Omaha, Nebraska 68127

Re: K080307
Trade/Device Name: ProChem Indicator Tape
Regulation Number: 880.2800
Regulation Name: Sterilization Process Indicator
Regulatory Class: II
Product Code: JOJ
Dated: April 9, 2008
Received: April 10, 2008

Dear Ms. Royalty-Hann:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

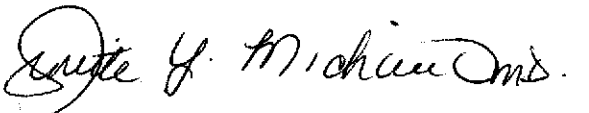
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k)
Number

Device Name ProChem Indicator Tape

Indications for Raven ProChem Indicator Tape is a process chemical indicator tape intended to seal packs and provide visual evidence that packs have been exposed when subjected to steam sterilization (121°C gravity cycles and 121°C – 134°C pre-vacuum cycles) processes as well as Harvey Chemiclave® chemical vapor sterilization process.

Prescription Use _____ AND/OR Over-The-Counter Use __X__
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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